SEP 2 5 2000

K001674

Section 9. SMDA 510(k) Summary

June 16, 2000

Trade Name:	Peripherally Inserted Central Catheter (PICC)
Common Name:	Gesco PICC
Classification:	Percutaneous Catheter (per 21 CFR 870.1250)

The Gesco® PICC is designed for use when longer-term central venous catheterization is prescribed. The silicone catheter is inserted peripherally by physicians or by specially trained nurses or nurse practitioners with the catheter tip residing in the superior vena cava.

The Gesco PICC is designed as a long-term (greater than 30 days), single-use, therapeutic intravascular catheter to provide central venous access for infusion of drug solutions, blood products or other fluids, and for blood sampling. It is used for critically-ill neonatal and small pediatric patients who require intravenous infusion of fluids, medications and nutritional therapy.

The Gesco PICC is substantially equivalent to the Per-Q-Cath® marketed by Bard Access Systems, Inc., the Neo♥PICC® marketed by Klein-Baker Medical, Inc. and the first PICC® marketed by Becton Dickinson Infusion Therapy Systems, Inc., among other devices.

Although there are slight differences in the dimensions and physical configuration of the predicate devices compared to the Gesco PICC, the intended use, indications for use, methods of use, materials, construction and performance characteristics are substantially the same. The Gesco PICC is as safe and effective a device for use in administering long term intravenous therapy as the predicate devices.

Kevin L. Cornwell
Chairman & CEO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2000

Mr. Kevin L. Cornwell
Chairman and Chief Executive Officer
Utah Medical Products, Incorporated
7043 South 300 West
Midvale, Utah 84047-1048

Re: K001874
Trade Name: Gesco PICC
Regulatory Class: II
Product Code: LJS
Dated: August 31, 2000
Received: September 1, 2000

Dear Mr. Cornwell:

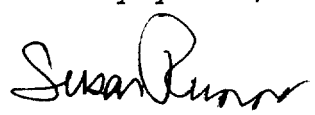
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3. INTENDED USE/ INDICATIONS for USE

510(k) Number: K001874

Device Name: Gesco® PICC

Intended Use:
The Gesco PICC is designed for use as a long-term (greater than 30 days), single-use, therapeutic intravascular catheter to provide central venous access for infusion of drug solutions, blood products or other fluids, and for blood sampling, for critically-ill neonatal and small pediatric patients who require intravenous infusion of fluids, medications and nutritional therapy.

Indications for use:
Gesco PICC is designed for use when longer-term central venous catheterization is prescribed.

Please refer also to Section 6, Labeling.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Irene Nawaw for PXC 9/7/00

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001874